

NCVHS/SPC Testimony

HIPAA Implementation Problems & Challenges for
Colleges and Universities:

Suggestions for Additional Clarification & Guidance

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Introduction

- Involvement/Knowledge re HIPAA
 - my work at UVM
 - participation in NACUA Presentations & Discussions
- These comments represent my personal views only, and not those of UVM, NACUA, or any other organization
- Most comments are informed by the thoughtful comments of others, and some refer to the experiences of others and particular concerns expressed by others

AREAS TO BE ADDRESSED

- The “FERPA” (student health records) Exemption
- Research Issues
 - Recruitment
 - Research Records
 - Accountings
 - IRB Waivers
- Interaction with Security Rule
- Other Issues

I. The FERPA Exception

- Definition of PHI excludes:
 - “Education Records” covered by FERPA, (i.e. any records or information directly related to a student maintained by an educational institution, with limited exceptions)
 - “Treatment Records” pertaining to a student that are carved out of the FERPA definition of “education records” [i.e. records relating to students attending post secondary schools that are kept by a physician or other health professional and are not available to any other person]

I. The FERPA Exception

MEANING

- All Student Health Records/Information held by Colleges and Universities are Exempt from HIPAA
- PHI in “Education Records” will be governed by FERPA & state law
- PHI in “Treatment Records” will be governed only by state law

I. The FERPA Exception

Problem: Some Colleges and Universities are not aware that FERPA, not HIPAA, will apply to some/all of their students' PHI.

- Confusion may be caused in part by DHHS Response to Comment in Preamble to 12/00 Final Rule (“...However, to the extent a school clinic is included within the definition of ‘health care provider’...and is engaged in HIPAA transactions, it will be a covered entity and must comply with the [Privacy] rules...”).
- DHHS presumably intended that statement to apply only to school clinics not covered by FERPA (i.e. clinics in schools not receiving Federal Financial assistance).
- Clarification would be very useful

I. The FERPA Exception

Problem: Many universities maintain clinics or provide health services to both students and non-students (e.g. spouses and dependents of students, faculty and staff, members of the community)

Effect

- Such clinics will need to develop and follow two different sets of policies and procedures for health records of students (FERPA – compliant) and health records of non-students (HIPAA-compliant).

I. The FERPA Exception

Problem

- FERPA and HIPAA policies and practices need to be separate and cannot practically be combined
- Some ways HIPAA & FERPA Differ
 - Content of authorizations (HIPAA) and consents (FERPA) differ
 - HIPAA gives patients right to review most all “treatment records.” Students have no such rights under FERPA.
 - Content of Business Associates Agreements (or their equivalent under FERPA) differ
 - Different rights and procedure re requests to amend records
 - No explicit minimum necessary rule under FERPA
 - Content and delivery of notices of privacy practices differ significantly
 - HIPAA permits unauthorized disclosures for certain uses & disclosures relating to TPO, research, public health, etc., but FERPA does not.
 - FERPA permits certain disclosures of PHI to teachers and school officials that HIPAA prohibits.

I. The FERPA Exception

Other Problems:

- Many university clinics do not distinguish between student and non-student patients in their registration, records or other procedures.
- One individual may receive services first while a student, and later as an employee or member of the public, or visa versa.

Effects

- Dual-population clinics will now need to distinguish between students and non-students in their registration and administrative practices.
- Clinics will need to establish separate record systems for students and non-students, or at least 2 sets of policies and procedures.
- For patients seen at different times as both students and non-students, either separate medical records must be kept, or the records must somehow be segregated into two parts.
- Confusing and burdensome on staff
- As practical matter, schools may choose to “opt-out” of HIPAA by (a) discontinuing treatment of non-students, (b) refusing to bill insurance and provide services on a cash-only basis, or (c) revert to exclusive paper-based billing system.

I. The FERPA Exception

Suggestion

- Reconsider DHHS position and state that HIPAA applies exclusively to student health records and information or permit schools to “opt into HIPAA and out of FERPA”.

Rationale

- Not inconsistent with Congressional intent – FERPA exception was created by DHHS, not Congress.
- Consistent with accepted rules of statutory construction – (1) two laws should be construed harmoniously to give maximum effect to both, and (2) the more specific statute (HIPAA which specifically concerns just health records and information) should take precedence over the more general statute (FERPA which generally concerns all student records held by a school). Both of these “rules” were cited by DHHS in the “Relationship with Other Federal Laws” section of 12/00 Preamble.
- Would eliminate difficult and costly burden of dual-compliance by clinics serving both populations and would lead to better and more appropriate treatment of student health records under HIPAA.

II. Research Issues

A. Recruitment of Research Subjects

(1) What is involved in “recruitment”?

- Dr A (researcher) getting PHI (e.g. patient names, addresses and medical condition info) from Dr B and Dr C (treating physicians) and/or from CE's records?
- Dr A or his/her staff contacting the patients through an appropriate procedure to see if would like to participate in a study?
- Answer: Both.

(2) Final Rule (8/02) Preamble states:

- Recruitment is not a health care operation (“HCO”) or a marketing activity.
- But use of PHI by the CE itself for research recruitment does not require individual authorization or an IRB waiver, since recruitment only involves disclosure of PHI to the patient
- Authorization or IRB Waiver is required only for disclosure to third party researcher/recruiter.

II. Research Issues

A. Recruitment of Research Subjects (cont.)

Ambiguities/Questions:

- Are DHHS Preamble statements consistent with 164.502, stating that only uses and disclosures enumerated by Rule are permitted?
- Did DHHS consider that recruitment usually involves access and use of PHI by staff of CE other than the patient's treating physician and staff?
- Where in Rule is authority given to Doctor A (Researcher) to obtain PHI about patients of Dr. B and Dr C (Clinicians), or from the CE's medical records, for purposes of research recruitment?

II. Research Issues

A. Recruitment (cont.)

(3) Preamble to Final Rule (12/00) states:

- In reviews preparatory to research, “only de-identified protected health information may be recorded by the researchers and the protected health information may not be removed from the premises of the covered entity.”

Ambiguity

- The underlined portion of above statement has no basis in the Final Rules of 12/00 or 8/02, but it seems to foreclose the possibility that researchers can access and record patient contact information for later use by them in recruiting patients when they are conducting a “review preparatory to research”

(4) Suggestions:

1. Interpret “HCO” or “marketing” to include research recruitment, or
2. Interpret “reviews preparatory to research” to include accessing, recording and using PHI for patient recruitment purposes, or
3. Amend Section 164.512(i) of the regulations to add a new subsection permitting the use and disclosure of PHI for the limited purposes of research recruitment.

II. Research Issues

A. Recruitment (cont.)

(5) The University-CE/Provider “Dual-Employment” Issue

Is access to practice’s/hospital’s PHI for recruitment purposes an internal “use” (not requiring authorization/waiver) or a “disclosure” to a third party when researcher is a “dual employee” of University (non-CE) and the separate practice/hospital (CE)?

- answer will determine whether Partial IRB waiver is required.
- what if the researcher is dually employed by the University and an entity in an OHCA with the CE (e.g. physician practice group) , but not by the CE itself (e.g. hospital)? Does that matter?
- does answer depend on which entity is considered to be actually “performing” the research? How would that be determined?

Suggestions:

- provide specific guidance on this issue
- permit dual employees in both cases to be treated as “internal users” of the CE’s PHI for research recruitment purposes
- would lessen administrative burdens and not significantly impact patient privacy rights.

II. Research Issues

B. Research Records

- ž Should Research Records (“RRs”)(i.e. records rec’d & maint’d by a researcher via authorization, IRB waiver, review preparatory to research, etc) containing PHI be treated differently than other (treatment) records?
- ž Most provisions of Privacy Rule facially apply to RRs held by a CE
 - possible exceptions – pt rt of access & rt to req amend, which apply only to “designated record sets”
- ž However, rules apply only to RRs held by a CE (or HCC of a HE); is this appropriate? Results in more favorable treatment of “outside” researchers.
 - Is there really a compelling need to have all of Pr Rule apply to RRs?
 - RRs already governed by privacy obligations in authorization “contract”, protocol conditions, IRB waiver and data use agreements.
- ž Heavy burden on researchers to administer compliance w/ Pr Rule provisions, e.g. accounting, min nec, bus ass (& pt access?). Would also require extensive training of rsrch staffs & identifying all research records
- ž Auth. already notifies pts that RRs may not be protected by Pr Rule.

Suggestion: Amend Pr Rule to require only that RRs be used/disclosed/maintained in acc w/ auth., waiver, use agreement and/or Pr Rule provs re to reviews prep to rsrch or rsch on decedent’s info.

II. Research Issues

C. Accounting of Disclosures

Question:

- ž In instances where a researcher is an employee of the CE, does the CE have to account for the “disclosures” of PHI to the researcher (pursuant to an IRB waiver or for a “review preparatory to research”) or is no accounting required because the access to PHI is considered a “use” of the PHI by the CE itself?
- ž Is the answer different if the researcher is a dual-employee of a University (non-CE) and a Hospital (CE), or a practice group in an OHCA with a Hospital (CE)? Does it depend on how the “research function” is delegated between the University and the CE? On the terms of researcher’s employment contract(s)? On where the PHI is kept? On some other factors?
- ž Answers will have a big impact on the administrative burden on CEs, since accounting for these common “internal” research disclosures/uses will require a great deal of time and effort not currently being expended.

II. Research Issues

D. IRB Waivers

- ž The second required finding/criterion for an IRB Waiver is “that the research could not practicably be conducted without the waiver or alteration”
- ž How should this be interpreted by IRBs and CEs in the context of waiver requests for studies in which obtaining of full authorizations from individuals purportedly would :
 - be too costly or would involve excessive time and effort leading to unacceptable study delay (e.g. studies involving the collection of information about large numbers of patients, perhaps from multiple providers)?
 - result in less than full, or less than acceptable, levels of participation by the target group, leading to biasing or failure of the study (e.g. population-based studies needing access to phi of all or nearly all individuals in the defined group)?

III. SECURITY RULE ISSUES

Problem: Proposed Security Rule does not recognize “Hybrid Entity” concept, and contains no FERPA Exemption.

Effects:

- Colleges and Universities units (e.g. counseling centers that do not bill insurance) not covered by Privacy Rule will still have to comply with Security Rule
- Student health records will be governed by Security Rule, even though they are exempt from Privacy Rule

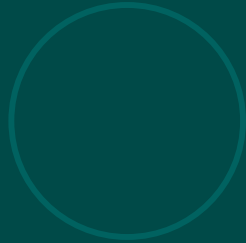
Suggestions: Include both concepts in Final Security Rule

IV. Other Issues

1. Universities Contracting With Providers to Deliver Health Services to University Staff or Students
 - ž When is the University the CE?
 - ž When is the Provider the CE?
 - ž What factors are key to this determination?
 - Who maintains ownership of the medical records?
 - Who engages in the HIPAA transactions?
 - At whose facilities the patients are seen?
 - How privacy duties are contractually assigned between the parties?
 - ž When does the FERPA exception apply to the physician's records, and when does it not?

IV. Other Issues

2. University Medical or Allied Health Students Serving as Student Interns at a Hospital/Provider that is a CE.
 - ž Does the University have to enter into a Business Associate Agreement with the CE?
 - ž The answer seems clearly to be NO, since the University would not be performing any function on behalf of the CE, but there are many reports of confusion and disagreement among schools and clinical sites.
 - ž Suggestion: Issue guidance clarifying this issue.



THE END